DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 31, 2014

Sterilucent, Inc.
Mr. Peter Kalkbrenner
Director of Engineering
1400 Marshall Street NE
Minneapolis, MN 55413

Re: K141312
Trade/Device Name: Sterilucent Process Challenge Device PCD-L for Lumen Cycle
Sterilucent Process Challenge Device PCD-NL for Non-Lumen Cycle
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: September 25, 2014
Received: October 3, 2014

Dear Mr. Kalkbrenner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141312

Device Name
Sterilucent Process Challenge Device PCD-L for Lumen Cycle
Sterilucent Process Challenge Device PCD-NL for Non-Lumen Cycle

Indications for Use *(Describe)*

The Sterilucent Process Challenge Device PCD-L for Lumen Cycle is used for performance qualification of the Sterilucent PSD-85 sterilizer during initial installation, after relocation, major repairs or malfunctions, or after sterilization process failures. The Sterilucent PCD-L may also be used for routine monitoring of the PSD-85 Sterilizer Lumen Cycle.

The Sterilucent Process Challenge Device PCD-NL for Non-Lumen Cycle is used for performance qualification of the Sterilucent PSD-85 Sterilizer during initial installation, after relocation, major repairs or malfunctions, or after sterilization process failures. The Sterilucent PCD-NL may also be used for routine monitoring of the PSD-85 Sterilizer Non-Lumen Cycle.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
for the
Sterilucent Process Challenge Device
K141312

Owner:	Sterilucent, Inc.
Address:	1400 Marshall Street NE Minneapolis, MN 55413
Telephone:	612-767-3260
Fax:	612-767-3261

Contact:	Peter R. Kalkbrenner Director of Engineering
Telephone:	612-767-3253
Fax:	612-767-3261

Summary Date: 25 September, 2014

1. Device Name and Classification

Trade Name:	Sterilucent Process Challenge Device PCD-L for Lumen Cycle Sterilucent Process Challenge Device PCD-NL for Non-Lumen Cycle
Common/Usual Name:	Biological Indicator (BI) Process Challenge Device
Classification Name:	Sterilization Process Indicator
Device Class:	Class II
Product Code:	FRC (21 CFR 880.2800)

2. Predicate Device

Steris Verify Biological Indicator Challenge Pack for Vaporized H2O2 Sterilization Processes (K092906)

3. Device Description

The Sterilucent PCD-L and PCD-NL are pre-assembled devices that consist of a Sterilucent Self-Contained Biological Indicator (SCBI), a vial, a vial cap containing a challenge tube, and a Chemical Indicator (CI) Label. The design of the PCD is such that it creates a challenge at least as challenging as the most difficult to sterilize item routinely processed in the PSD-85 sterilizer.

The PCDs are used by healthcare providers for qualification testing of the Sterilucent PSD-85 sterilizer and for routine monitoring of the PSD-85 sterilizer Lumen and Non-Lumen Cycles.

The user places the Sterilucent PCD into the Sterilucent PSD-85 along with a load and initiates a sterilization cycle. After cycle completion, the PCD is retrieved. The CI is immediately accessed for a passing color change from pink to blue. If the CI is blue, the SCBI is removed from the PCD vial and activated by breaking the glass ampoule which contains a growth media. The SCBI is then incubated at 60°C ± 2°C for 18 hours and monitored for any color change. The appearance of a yellow color in the media indicates bacterial growth (a failing result); no color change indicates adequate sterilization (a passing result).

4. Statement of Intended Use

The Sterilucent Process Challenge Device PCD-L for Lumen Cycle is used for performance qualification of the Sterilucent PSD-85 sterilizer during initial installation,

after relocation, major repairs or malfunctions, or after sterilization process failures. The Sterilucent PCD-L may also be used for routine monitoring of the PSD-85 Sterilizer Lumen Cycle.

The Sterilucent Process Challenge Device PCD-NL for Non-Lumen Cycle is used for performance qualification of the Sterilucent PSD-85 Sterilizer during initial installation, after relocation, major repairs or malfunctions, or after sterilization process failures. The Sterilucent PCD-NL may also be used for routine monitoring of the PSD-85 Sterilizer Non-Lumen Cycle.

5. Technological Characteristics Summary Comparison

The Sterilucent PCD technological characteristics are substantially equivalent to the predicate device as summarized in the table below. Each include an SCBI containing at least 10^6 spores of *Geobacillus sterathermophilus* (the most resistant organism for vaporized hydrogen peroxide sterilization), an ANSI/AAMI/ISO 11140-1 Class 1 Chemical Indicator appropriate for vaporized hydrogen peroxide sterilization, and device specific packaging which increases the resistance of the packaged BI to represent a challenge greater than or equal to the worst-case biological model used to validate the respective sterilizer in which the challenge device is to be used.

Technological Characteristic	***Proposed Device*** **Sterilucent Process Challenge Device**	***Predicate Device***
Sterilization Modality	Vaporized hydrogen peroxide	Same
Biological Indicator Organism	SCBI containing at least 10^6 spores of *Geobacillus sterathermophilus*	Same
Process Indicator	Class 1 Chemical Indicator per ANSI/AAMI/ISO 11140-1	Same
Packaging (Mechanism to Increase the Resistance of the BI)	The SCBI is packaged in a vial. The vial is plugged on one end, while the other end contains a hole through which a diffusion-restricting challenge tube is inserted.	The SCBI is packaged with a sheet of foam and placed within a Tyvek pouch.
Resistance Characteristics	The Sterilucent Process Challenge Device is more resistant to the Sterilucent PSD-85 sterilization processes (Lumen and Non-Lumen Cycles) than is the biological model developed for validation of those sterilization cycles.	The Verify Biological Indicator Challenge Pack for Vaporized Sterilization Processes is more resistant to the V-PRO 1 and V-PRO 1 Plus (Lumen and Non-Lumen Cycles) sterilization processes than is the biological model developed for validation of those sterilization cycles.

6. Summary of Non-Clinical Performance Data

The Sterilucent Process Challenge Device, PCD-L and PCD-NL, have been evaluated for resistance to the Sterilucent PSD-85 Lumen and Non-Lumen cycles respectively. These PCDs are at least as resistant to the sterilization process as the biological model

used to validate the PSD-85 sterilizer. This determination is based on fraction-negative data from the PCDs biological indicator as a function of sterilant dose. PCDs from three separate manufacturing lots were exposed to PSD-85 Lumen and Non-Lumen half-cycles with decreasing doses of sterilant. The response of the PCDs chemical indicators during these exposures was also determined adequate.

7. Overall Performance Conclusion Statement

The Sterilucent Process Challenge Devices have the necessary resistance relative to the biological model to be an appropriate challenge to qualify the PSD-85 Lumen and Non-Lumen Cycles. The Sterilucent PCDs are substantially equivalent to the predicate device.